

TOYA145.001APC

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: CHIKARA et al.

Application No.: 10/566,829

Filing Date: January 31, 2006

For: PHARMACEUTICAL COMPOSITION FOR ORAL
ADMINISTRATION

Art Unit: 1614

Examiner:

RICCI, CRAIG D

Attorney DOCKET No.:

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DECLARATION UNDER 37 C.F.R. § 1.132

Commissioner for Patents

P.O.Box 1450

Alexandria, VA 22313-1450

Dear Sir:

I declare as follows:

1. I am employee of Nichi-Iko Pharmaceutical Co., Ltd. located at 1-6-21, Sogawa, Toyama-shi, Toyama, Japan, which is engaged in the business of development of drugs.
2. I am one of co-inventors of the above-identified patent application.
3. It is necessary to add D-sorbitol to prepare a jellied composition containing granisetron hydrochloride as an active ingredient. However, there arises a problem of foaming when D-sorbitol is combined with granisetron hydrochloride. In order to solve this problem, I searched a further ingredient which solves this foaming problem.
4. I have conducted the experiments described herein and present them as evidence supporting the above facts.
5. Purpose of the experiments
Comparing the defoaming effect of glycerin with another polyalcohol, propylene glycol

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6. Methods and results of the experiments

The ingredients shown in the table were added into appropriate amounts of water to prepare each of the solutions. Each of the solutions was shook up to allow foaming. Then, the time from the start of the foaming to disappearance of the foam was measured.

	①	②	③	④	⑤	⑥	⑦
granisetron hydrochloride (w/w)%	0.112	0.112	0.112	0.112	0.112	0.112	0.112
D-sorbitol (w/w)%	28	28	28	28	28	28	28
glycerin (w/w)%	.	11.1	12.1	13.1	.	.	.
propylene glycol (w/w)%	11.1	12.1	13.1
pure water (w/w)%	appropriate amount	appropriate amount	appropriate amount	appropriate amount	appropriate amount	appropriate amount	appropriate amount
defoaming time (sec.)	12	8	6	4	11	12	16

7. The result shows that glycerin significantly shortened the defoaming time of the composition comprising D-sorbitol and granisetron hydrochloride in a dose-dependent manner. This effect is specific to glycerin because propylene glycol did not shorten the defoaming time. The effect of glycerin could have never been expected.

8. I further declare that all statements made herein of our own knowledge are true, and that all statements made on information and belief are believed to be true, and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

By: M. Naito
(Name)

Date: September 28, 2009